

TRANSDERMAL CONTRACEPTIVE PATCH

I. INTRODUCTION

Oral contraceptive pills are very popular and effective, but poor compliance results in a significant rate of pregnancy. The transdermal contraceptive patch was developed to provide a similar reversible contraceptive with a more convenient dosing schedule that would enhance patient compliance and achieve high contraceptive efficacy.

The transdermal contraceptive patch is a matchbook size, beige-colored transdermal contraceptive patch that contains both estrogen and progestin. The patch has a contact surface area of 20 cm² and consists of 3 layers. The outer layer consists of polyethylene/polyester and provides support for the middle layer, which contains the hormones. The third layer is a clear lining that protects the adhesive layer and is removed before use. Each patch contains 6.00 mg norelgestromin and 0.75 mg ethinyl estradiol, and releases 150 mcg of norelgestromin and 20 mcg of ethinyl estradiol to the bloodstream per 24 hours.

When applied to the skin, the patch delivers the two active ingredients into the systemic circulation. Because the patch is a transdermal delivery system, the doses of estrogen and progestin delivered cannot be compared with the doses of estrogen and progestin in an oral contraceptive. The primary mechanism of action is inhibition of ovulation. In addition, the contraceptive patch produces an endometrium that is not receptive to ovum implantation, and cervical mucus which becomes thick and hostile to sperm transport. Tubal and endometrial motility are also slowed.

Perfect use failure rate in the first year of use: 0.3%

Typical use failure rate in the first year of use: 9%

Patients using the patch should receive counseling about and, as needed, prescriptions for emergency contraception.

On September 20, 2006, the FDA announced that a revised “bolded” warning was added to the labeling of the transdermal contraceptive patch. This warning states that a patient using the patch will be exposed to about 60% more estrogen than if the patient had been using a typical birth control pill containing 35 mcg of estrogen. The risk of venous thromboembolic disease (blood clots in the legs and/or the lungs) may be increased with transdermal contraceptive patch compared with that of oral contraceptives containing a norgestimate and 35 mcg of estrogen. In one study the risk was 2-fold. All clients must be counseled on this possible increased risk. Overall, risk of DVT with use of the patch is much less than the risk of DVT during pregnancy.

OrthoEvra® has been discontinued in the United States – now replaced by generic - Xulane® which was FDA approved in 2014.

II. TRANSDERMAL CONTRACEPTIVE PATCH DOSING SCHEDULE

Recommended dosing is one patch applied once weekly for three consecutive weeks (21 days), followed by 1 patch-free week per cycle. Patches should be removed or changed on the same day each week.

- A. The patch is worn for 7 days (1 week). On the “Patch Change Day” (Day 8), the used patch is removed and a new one is applied immediately.
- B. A new patch is applied for Week 2 (on Day 8) and again on Week 3 (Day 15), on the usual “Patch Change Day”. Patch changes may occur at any time on the “Patch Change Day”. Each new patch should be applied to a new spot on the skin to help avoid irritation, although they may be kept within the same anatomic area.
- C. Week 4 is patch-free (Day 22 through Day 28), thus completing the 4-week cycle. Vaginal bleeding is expected to begin during this time.
- D. The next 4-week cycle is started by applying a new patch on the usual “Patch Change Day”, the day after Day 28, no matter when the menstrual period begins or ends. Under no circumstances should there be more than a 7-day patch-free interval between cycles. If more than 7 days pass, the client may be a candidate for emergency contraception if intercourse has occurred within the past 5 days.

III. CLIENT SELECTION

Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for COCP or to MEC Guidelines at: <https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/summary.html>

- A. Appropriate candidates for transdermal contraceptive patch use include:
 - 1. Any client who meets criteria for any of the estrogen/progestin contraceptives.
 - 2. Any client who expressed a preference for this method and/or who cannot remember to take the pill, objects to vaginal ring use, does not like shots or use local contraception at the time of intercourse.
- B. Consider the precautions prior to prescribing transdermal contraceptive patches (Appendix C). Refrain from providing transdermal contraceptive patches to those with major risk factors and use caution in prescribing for those with relative risk factors.
- C. Clients with a history or presence of hypersensitivity in response to topical bandages or adhesive applications should be excluded.
- D. In clients over age 35 or those with a family history of premature death from cardiovascular disease, obtaining a lipid profile and fasting blood sugar prior to prescribing combined oral contraceptives can be considered particularly if client has not been tested for diabetes or dyslipidemia before.
- E. Be cautious in prescribing transdermal contraceptive patches for clients with oligomenorrhea or amenorrhea. They may have an underlying medical condition. Unless such a client’s diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
- F. The ADA recommends that health care providers consider screening patients for diabetes at 3-year intervals beginning at age 45, particularly in those with BMI

- ≥25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipidemia.
- G. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.
 - H. The contraceptive patch may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormone contraceptive while breastfeeding. For non-breastfeeding clients the contraceptive patch may be initiated at 4 weeks postpartum. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
 - I. Clients must be counseled that the contraceptive patch may be less effective in women with a body weight of 198 lbs. or more. Weight >198 pounds is not an absolute contraindication to use of the patch. Women who weigh more than 198 pounds should be counseled about and encouraged to use other, more effective, methods of contraception. However, if the client requests the patch, she should be provided with this method and you should document your counseling.
 - J. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).

IV. TRANSDERMAL CONTRACEPTIVE PATCH INITIATION

- A. Patients starting on the patch are not required to have a pelvic examination. Access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. If a client is starting the contraceptive patch for the first time, she should wait until the day she begins her menstrual period. A Quickstart, First Day start or a Sunday start may be chosen. The day she applies her first patch is Day 1. Her “Patch Change Day” will be this day every week.
- C. **Quickstart protocols are highly encouraged** when a patient is starting (or restarting) the patch. Quickstart improves compliance with starting the second month of contraception, and may decrease risk of unintended pregnancy.
- D. Quickstart:
 - 1. Start the first patch on the day of the visit.
 - 2. A back-up method of contraception is recommended for 7 days.
 - 3. If the client is in need of emergency contraception, she should take both tablets of Plan B® at once on the visit day and start her patch no later than the next day.
 - 4. Her next menses may be delayed until she completes her first 3 patches.
 - 5. Quickstart does not increase irregular spotting or bleeding.
 - 6. The client should check a pregnancy test if she has not seen a normal menses within 4 weeks of starting the patch.
- E. First-day start:
 - 1. The client should apply her first patch during the first 24 hours of her menstrual period.

2. No back-up contraception is needed.
- F. Sunday start:
 1. The client should apply her first patch on the first Sunday after her menstrual period starts.
 2. She must use condoms as back-up contraception for the first week of her first cycle.
 3. If the menstrual period begins on a Sunday, the first patch should be applied on that day and no back-up contraception is needed.
- G. Postpartum, breastfeeding women should not use transdermal contraceptive patch.
- H. Postpartum, non-breastfeeding women
 1. In women who are <21 days postpartum, use of combined hormonal contraceptives should not be used (USMEC category 4).
 2. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
 3. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
 4. Do not wait for client's first menses, as most women will have ovulated before first menstruation.

I. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a transdermal contraceptive patch should receive the following:

- A. Information/counseling regarding all contraceptive options available.
- B. Information specific to hormonal contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
- E. Instruction on how to select a site for patch application and how to apply patch (see section below and refer to Patient Package Insert).
- F. Instruction on what to do if patch becomes detached or client forgets to put a new patch on. Additionally, for some situations the use of emergency contraceptive pills may be considered.
- G. Information that contraceptive patch does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- H. Informed consent (form available as a stand-alone document) should be reviewed and signed and a copy of the same upon request.
- I. If transdermal contraceptive patch is being provided/prescribed, then CHC consent form (available a stand-alone document) should be reviewed and signed.

- J. If transdermal contraceptive patch is being provided/prescribed to a client with risk factors, then a Request for CHC for Women with Risk Factors form should be reviewed and signed.
- K. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- L. Emergency, 24-hour telephone number and location where emergency services can be obtained.
- M. Clinic access information.

V. INSTRUCTIONS FOR PATCH PLACEMENT AND APPLICATION

- A. Choosing a placement site for patch:
 1. The patch should be applied to clean, dry, intact, healthy skin on the buttock, abdomen, upper outer arm or upper torso, in a place where it will not be rubbed by tight clothing. The patch should not be placed on the breasts.
 2. The patch should not be placed on skin that is red, irritated or cut.
 3. To prevent interference with the adhesive properties of the patch, no make-up, creams, lotions, powders or other topical products should be applied to the skin area where the patch is or will be placed.
 4. No adhesive products should be placed over the patch.
 5. The patch should not be drawn on with any kind of pen, pencil or marker.
 6. The patch should not be placed on a tattoo.
- B. Instructions for patch application:
 1. The foil pouch is opened by tearing it along the top edge and one side edge.
 2. The foil pouch should be peeled apart and opened flat.
 3. A corner of the patch is grasped firmly and it is gently removed from the foil pouch. The patch is covered by a layer of clear plastic. It is important to remove the patch and the plastic together from the foil pouch. Sometimes patches can stick to the inside of the pouch – the client should be careful not to accidentally remove the clear liner as she removes the patch.
 4. Half of the clear protective liner is to be peeled away, being careful not to touch the exposed sticky surface of the patch with the fingers.
 5. The sticky surface of the patch is applied to the skin and the other half of the liner is removed. The client should press down firmly on the patch with the palm of her hand for 10 seconds, making sure the edges stick well. She should check her patch every day to make sure it is sticking well.

VI. INSTRUCTIONS FOR MANAGEMENT OF INADVERTENT PATCH DETACHMENT, PROLONGED USE PERIOD OR PROLONGED PATCH-FREE PERIOD

A patch should not be reapplied if it is no longer sticky, if it has become stuck to itself or another surface, if it has other material stuck to it or if it has previously become loose or fallen off. If a patch cannot be reapplied, a new patch should be applied immediately. Supplemental adhesives or wraps should not be used to hold the patch in place.

- A. If a patch is partially or completely detached for less than 1 day (24 hours):
 1. The woman should try to reapply it to the same place or replace it with a new patch immediately.
 2. The “Patch Change Day” will remain the same.

3. No back-up contraception is needed.
- B. If a patch is partially or completely detached for more than 1 day (24 hours or more) or if a woman is not sure how long the patch has been detached:
 1. She should remove the old patch and apply a new patch immediately.
 2. The new "Patch Change Day" and new "Day 1" is the day the replacement patch is applied.
 3. Back-up contraception must be used for the first 7 days of the new cycle.
 4. The client may be a candidate for emergency contraception if intercourse has occurred within the past 5 days.
- C. If a woman forgets to apply a patch at the start of any patch cycle (week 1/day 1):
 1. She should apply the new patch of her new cycle as soon as she remembers.
 2. There is now a new "Patch Change Day" and a new "Day 1".
 3. Back-up contraception must be used for the first 7 day of the new cycle, and the client may be a candidate for emergency contraception.
- D. If a woman forgets to change her patch in the middle of the patch cycle (week 2/day 8 or week 3/day 15) for 1 or 2 days (up to 48 hours):
 1. She should remove the old patch and apply a new patch immediately.
 2. The next patch should be applied in the usual "Patch Change Day".
 3. No back-up contraception is needed.
- E. If a woman forgets to change her patch in the middle of the patch cycle (week 2/day 8 or week 3/day 15) for more than 2 days (48 hours or more):
 1. She should remove the old patch and apply a new patch immediately.
 2. She should stop the current contraceptive cycle and start a new four-week cycle immediately by putting on a new patch. There is now a new "Patch Change Day" and a new "Day 1".
 3. Back-up contraception must be used for the first 7 days of the new cycle, and the client may be a candidate for emergency contraception if intercourse has occurred in the past 5 days.
- F. If a woman forgets to remove her patch at the end of the patch cycle (week 4/day 22),
 1. She should remove the patch as soon as she remembers.
 2. The next cycle should be started on the usual "Patch Change Day", which is the day after Day 28.
 3. No back-up contraception is needed.
- G. If a woman wishes to change her "Patch Change Day":
 1. She removes her third patch on the correct day.
 2. She may select an earlier "Patch Change Day" by applying a new patch on the desired day.
 3. In no case should there be more than 7 consecutive patch-free days.
- H. The patient should still see a period of bleeding each month. If this is delayed, or if she has unusual or abnormal bleeding, she should check a pregnancy test immediately.

VII. INSTRUCTIONS FOR CONTRACEPTIVE PATCH STORAGE, DISPOSAL AND DISPENSING

- A. Contraceptive patches should be stored at room temperature.
- B. Contraceptive patches should be removed from their protective pouches only when it is time to apply them to the skin.

- C. Each used patch should be folded in half so that it adheres to itself before discarding it in a place inaccessible to children and pets, because used patches still contain some active hormones.
- D. Dispensing instructions for transdermal contraceptive patch:
 - 1. Give the new **Xulane®** client a 1-3 month supply of **Xulane®**, and a prescription for a year's supply. Review the product insert with the client.
 - 2. When the need arises, an extra patch may be provided from the clinic supply or a prescription may be given for one patch.
 - 3. Recommend the routine use of condoms to decrease the risk of acquiring sexually transmitted diseases.

VIII. FOLLOW-UP

- A. The client should return in 1-3 months for evaluation of patch continuation. The client should have a blood pressure check and be evaluated for side effects. For cost containment purposes, it is recommended that the client be given no more than 3-6 months supply of patches at any one time. However, patients may be provided a prescription for a year's supply so that access to her method of contraception is not limited.
- B. Clients can be provided the educational handout on Combined Hormonal Contraception which reviews side effects and warnings signs requiring evaluation which (available as stand-alone document).
- C. Serious side effects that may warrant immediate consultation and discontinuation of combined hormonal contraceptives include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - 2. Pain in calf or leg
 - 3. Crushing chest pain or tightness in the chest
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - 5. Sudden partial or complete loss of vision
 - 6. Breast masses suspicious for potential malignancy
 - 7. Severe abdominal pain or tenderness
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood
 - 9. Jaundice

IX. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.

- A. Minor side effects of contraceptive patch use may occur:
 - 1. Skin irritation, redness or rash may occur at the site of the application. The patch may be removed and a new patch may be applied to a new location until the next "Patch Change Day".
 - 2. Breakthrough bleeding or spotting may occur. This is usually limited to the first few cycles. The client should be advised to call the clinic to discuss her bleeding pattern prior to discontinuing the patch.
 - 3. Other common side effects include nausea and vomiting, breast tenderness, headache, menstrual cramps, abdominal pain, changes in appetite,

nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal discharge.

- B. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, the contraceptive patch should be removed immediately and further evaluation is warranted.
- C. Other reasons for stopping the contraceptive patch:
 - 1. If major surgery or immobilization for an extended period of time is contemplated, the client should discuss discontinuing the use of the contraceptive patch with her surgeon.
 - 2. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP >160-100 are reasons to discontinue the contraceptive patch and refer the client for medical evaluation.
 - 3. With evidence of severe clinical depression, stop the contraceptive patch and refer the client for psychiatric evaluation. For mild mood changes a different estrogen/progestin contraceptive may be offered.
- D. Any client with post-patch amenorrhea of more than 6 months should be referred for evaluation.
- E. With 28-day cycling, one missed period with a negative pregnancy test may be managed by reassurance or a change in estrogen/progestin contraceptive. After 2 or more missed periods the client should be examined. Consideration may be given to additional evaluation and/or a change in contraception.
- F. Any client desiring to become pregnant may be advised to use contraceptive ring until pregnancy is desired. Fertility may return immediately following discontinuation of the ring. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.
- G. If a woman using a contraceptive patch misses a period, she should not remove her patch or stop her patch cycle. A urine pregnancy test may be obtained. The patch should be discontinued if pregnancy is confirmed.

X. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Contraceptive patches dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

REFERENCES

- 1. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 57, No. RR-4, June 18, 2016.
- 2. ACOG. Committee Opinion. Access to Contraception. 2015.
- 3. ACOG. Guidelines for Women's Health Care: A Resource Manual, 4th Edition. 2014.

4. Hatcher RA et al. Contraceptive Technology. 20th Revised Edition. Ardent Media, Inc., New York, 2011.
5. Manufacturer's FDA Product Patient Insert

POSSIBLE HEALTH BENEFITS OF THE CONTRACEPTIVE PATCH

The possible health benefits of the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis
11. Possible decreased number of sickle cell crises

APPENDIX B

POSSIBLE HEALTH RISKS OF THE CONTRACEPTIVE PATCH

The possible health risks of the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gallbladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use the transdermal contraceptive patch should be strongly advised not to smoke.

APPENDIX C

PRECAUTIONS IN PROVIDING THE CONTRACEPTIVE PATCH

The precautions in providing the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

Refrain from providing the transdermal contraceptive patch for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Valvular heart disease with complications
5. Severe hypertension (>160/100 mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Migraine headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history of breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute or chronic hepatocellular disease with abnormal liver function. Women who are hepatitis carriers, or who have had a history of hepatitis, but now have normal liver function may use estrogen-containing birth control.
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Postpartum <21 days or 21-42 days postpartum with other risk factors for venous thromboembolism (VTE)
16. Hypersensitivity to any component of the transdermal contraceptive patch
17. Multiple risk factors for atherosclerotic cardiovascular disease (e.g. older age, smoking, diabetes, hypertension, low HDL, high LDL or high triglyceride levels)

Exercise caution in providing the transdermal contraceptive patch for women with:

1. Severe headache/migraine without aura
2. Hypertension
3. Active gallbladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Hyperlipidemia or history thereof
7. Lactation
8. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
9. Amenorrhea or oligomenorrhea
10. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
11. Undiagnosed vaginal/uterine bleeding
12. Cardiac or renal disease or history thereof
13. Over 50 years of age
14. Family history of the death of a parent or sibling due to myocardial infarction before age 50

APPENDIX D

DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples are included below but may not be all inclusive so provider should check for potential drug interactions whenever prescribing the transdermal contraceptive patch:

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- Barbiturates (Phenobarbital)
- Griseofulvin
- Rifampin
- Phenylbutazone (Butazolidin®)
- Primidone (Mysoline®)
- Phenytoin (Dilantin®)
- Carbamazepine (Tegretol®)
- Felbamate (Felbatol®)
- Oxcarbazepine (Trileptal®)
- Topiramate (Topamax®)
- St. John's Wort
- Anti-HIV protease inhibitors